AMERICAN REGENT™

February 28, 2020

Via E-mail: AGO.highcostprescriptiondrugs@vermont.gov

Re: New Drug Introduction Report Pursuant to 18 V.S.A. § 4637(c)

To Whom It May Concern:

On January 28, 2020 pursuant to 18 V.S.A. § 4637(b), American Regent, Inc. (ARI) submitted a new drug introduction notice for the following product:

NDC	Product Description
00517-6103-25	ZINC SULFATE INJECTION, USP 30MG/10ML (3MG/ML), PKG OF 25
00517-8005-25	ZINC SULFATE INJECTION USP, 25MG/5ML (5MG/ML), PKG OF 25

ARI now provides additional information pursuant to 18 V.S.A. § 4637(c). Per the requirements, we have limited the information we are reporting here to that which is publically available or otherwise available in the public domain.

1. **US and international marketing and pricing plans used at launch**: We do not have plans to conduct any substantial marketing activities related to the new product. We do not have any plans to conduct any direct-to-consumer advertising for the product. Our marketing efforts to promote the new drug to physicians and other health care professionals are limited to marketing on our website as well as a digital announcement to announce the availability of the new product. American Regent sells its products directly to wholesalers, distributors and closed door pharmacies. American Regent also sells it product indirectly to several entities, including independent pharmacies, managed care organizations, hospitals, etc. These customers, called, "indirect customers," purchase our products primarily through our wholesale customers. The Product has not yet launched in any international jurisdiction.

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A Daiichi Sankyo Group Company

1. **Estimated volume of patients:** Estimated Patients per NDC: 26,250 – The new product line is approved by the FDA to treat Zinc deficiency. It is administered intravenously as part of a parental nutrition regiment. It is estimated that the volume of patients that receive parental nutrition is over 290,000 hospital stays per year and that an additional 25,000 patients receive parental nutrition at home. If we assume that each hospital stay represents one unique patient then this total is 315,000 patients annually or 26,250 per month. We do not know how many of those potential patients might be prescribed the drug.

2. **Whether the FDA granted breakthrough therapy designation or priority review:** The product did not receive a breakthrough therapy designation or priority review.

3. **Date and price of acquisition**: Not applicable. ARI developed the product.

ARI provides this report consistent with its understanding and interpretation of 18 V.S.A. § 4637 and its provisions. In providing this report, ARI does not waive any rights it may have at law or in equity with respect to 18 V.S.A. § 4637, its interpretation, and/or its application to ARI or any of its affiliates, now or in the future. ARI, on behalf of itself and its affiliates, expressly reserves all such rights. Per the requirements we have limited the information we are reporting here to what is available or otherwise available in the public domain.

Thank you for your consideration,

Gale A. Lynch

Gale A. Lynch
Manager, Government Pricing